DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4500
FAX: 504-253-4566

December 15, 2000

WARNING LETTER NO. 2001-NOL-05

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Lynn B. Nguyen, Co-Owner
C & J Seafood, Inc.
116 North Hollywood Road
Houma, Louisiana 70364-2806

Dear Mrs. Nguyen:

We inspected your firm, located at 116 North Hollywood Road, Houma, Louisiana, on October 16-18, 25, 2000, and found that you have serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations [Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123)]. These deviations, some of which were previously brought to your attention, cause your processed crabmeat to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

- You must take an appropriate corrective action when a deviation from a critical limit (CL) occurs, in order to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen growth when your process for ready-to-eat crabmeat deviated from your CL at the cooler storage critical control point (CCP).

- You must implement the monitoring procedures listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures for monitoring temperature records for the cooler at the cooler storage CCP to control pathogen growth nor monitor the amount of time cooked crab products are exposed to unrefrigerated conditions at the backing, picking, and packing critical control points (CCPs) as required by your HACCP plan for ready-to-eat crabmeat.

- You must have a HACCP plan that lists the critical limits (CLs) that must be met, in order to comply with 21 CFR 123.6(c)(3) . However, your firm's HACCP plan for ready-to-eat crabmeat lists a CL of [redacted] at the overnight cooler storage CCP that is not adequate to control pathogen growth.

- You must implement the record keeping system listed in your HACCP plan, in order to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the cook process, backing, picking, packing, and shipping CCPs listed in your HACCP plan.

- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.8(a)(2). However, your firm did not identify calibration of the temperature recorder in the cooler as an ongoing verification procedure of the CL of maintaining cooler temperature at the cooler storage CCP to control pathogen growth.

- You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor for the prevention of cross-contamination from insanitary objects to food with sufficient frequency to ensure control, as evidenced by improper employee practices, some of which follow: An employee touched an insanitary item and then touched cooked product without first washing and sanitizing his hands. An employee used a knife, that had fallen into a dirty trashcan, to pick cooked crabmeat without first washing the knife. Employees routinely handled cooked crab product after coming into contact with insanitary items, and only dipping their hands, gloves, and utensils in sanitizer without first washing them. On nine occasions your employees were observed to rub their noses/faces with their gloved hands and then resume picking without first washing or sanitizing their hands. Similar deviations were brought to your attention in our letters of October 2, 1998 and February 11, 2000.

- You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor the condition and cleanliness of food contact surfaces and equipment, with sufficient frequency to ensure control, as evidenced by the following observations. Pieces of crabs from previous operations were wedged between the metal bars and the two rims inside the reel washer at the beginning of backing operations. Residues from previous operations were encrusted on the rough abraded surfaces of the plastic crates used to hold cooked crab product. The metal chain and sprocket for the reel washer are rusty. Rust, scaly mineral residues, and a white substance were encrusted on the metal icemaker exit chute. A knife, with black residues encrusted in its etched handle, was used to crack and pick crab claws. Similar deviations were brought to your attention in our letters of October 2, 1998 and February 11, 2000.

- You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your firm did not complete any sanitation control records regarding improper employee practices or the condition and cleanliness of food contact surfaces and equipment, as described in the two preceding paragraphs.

- You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor exclusion of pests from the food plant with sufficient frequency to ensure control, as evidenced by live flies inside the plant during operations and direct structural openings to the outside which would allow pest entry.

- You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not adequately monitor maintenance of hand sanitizing with sufficient frequency to ensure control as evidenced by no detectable amount of chlorine in the pickers' hand dip bowls and the use of a chlorinator not indicated for use as a sanitizer

in food processing plants. Similar deviations were brought to your attention in our letter of February 11, 2000.

At a meeting with the New Orleans District staff on August 11, 2000, and in letters from FDA, dated August 13, 1997, October 2, 1998 and February 11, 2000, you were notified of similar deficiencies as described in this letter. During the inspections, and in the letters noted above, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in three years time, your firm has not taken action to completely and permanently correct these deficiencies.

We acknowledge your November 7, 2000, response to the FDA Form 483 issued at the close of our inspection. Your response addressed some, but not all of our concerns. The corrections you described will be verified at a future inspection of your firm.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigator documented this commitment by annotation of the Form FDA 483. However, please respond to this office in writing within three (3) weeks from receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as: your revised HACCP plan, copies of your monitoring records, copies of corrective action data, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,

Carl E. Draper

Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA-483